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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,644	09/07/2001	Andreas Bitterhof	DFS-129-A	2087

7590

04/05/2005

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EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/937,644	Applicant(s) BITTERHOF, ANDREAS	
	Examiner Patricia C. Mallari	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is a final Office action. Any new grounds of rejection were necessitated by the applicant's amendment to the claims.

Claim Objections

Claims 1, 2 and 15 are objected to because of the following informalities:

on line 8 of claim 1, "the analysis means" should be replaced with "the analysis device";

on line 11 of claim 1, "the separating means" should be replaced with "the means for disposing";

on line 2 of claim 2, "the separating means" should be replaced with "the means for disposing";

on line 3 of claim 15, "measuring" should be replaced with "means for measuring". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 4-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 recites, "means for disposing the analysis device on the absorbent

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element" on lines 8-9 of the claim. While the applicant discloses that the analysis device "is disposed on the hygiene item" (paragraph 0010 of the instant application), the applicant fails to teach a means (structure or instrument) for doing so. Also, claim 5 recites the limitation, "wherein the edges of the insert are folded over on an upper side of the analysis device." However, the specification states that "Edges 12 of the insert 2, which connect to the sidewalls 20, are folded over to the inside on one top side 12" in paragraph 0019 but fails to state that the edges are folded over on an upper side of the analysis device 4. Figures 1 and 3 of the instant application also fail to show the edges 12 being folded over on an upper side of analysis device 4.

The applicant should further note that addition of language to the instant application in order to provide support for the limitations in claims 1 and 5 identified above would result in an objection under 35 U.S.C. 132 as an introduction of new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,126,597 to Smith et al. Smith discloses an analysis device comprising a visual display unit 26, 34, a means 34 for measuring composition of bodily fluids directly introduced into the analysis device associated with the visual display device 26, 34, and means 26, 28 for maintaining the analysis device in separate fluid-tight contact with a single-use hygiene item 12 (figs. 1-3; col. 4, lines 28-49; col. 5, lines 1-47; col. 5, line 65-col. 6, line 10 of Smith), wherein means 28 may be composed of a polyethylene film (figs. 2 & 3; col. 5, lines 1-4 of Smith), which is liquid impervious (See col. 3, lines 51-52 of SIR H1298 to Ahr et al. for a teaching of polyethylene as liquid impervious).

The applicant should note that the limitations regarding the single-use hygiene item (i.e. "the single-use hygiene item including . . .") fail to bear any patentable weight since the claim does not positively claim the single-use hygiene item.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6-9, 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,126,597 to Smith et al. in view of US Patent No. 5,344,698 to Rock et al.

Smith teaches a hygiene item, in the form of an undergarment or panty, comprising an absorbent element 12 (col. 4, lines 26-31 of Smith) configured to absorb

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and retain bodily fluid passed by a user. An analysis device 24, 34, for analyzing at least one characteristic (pH) of bodily fluid passed by the user (col. 5, line 66-col. 6, line 10 of Smith), facilitates direct impingement of a portion of the bodily fluid passed by the user into contact with the analysis means separate from contact with the absorbent element (figs. 1-2; col. 4, lines 50-53 of Smith). The construction of element 10, including layers 26 and 28 serves as means for disposing the analysis device 24, 34 on the absorbent element 12 (fig. 3; col. 4, lines 33-36; col. 6, lines 42-44 of Smith) and is configured for separating bodily fluid in the analysis device 24, 34 in an essentially fluid-tight manner, wherein means 28 may be composed of a polyethylene film (figs. 2 & 3; col. 5, lines 1-4 of Smith), which is liquid impervious (See col. 3, lines 51-52 of SIR H1298 to Ahr et al. for a teaching of a polyethylene film as liquid impervious). Since part of the separating means 26, 28 is liquid impervious and placed between analysis device 34 and absorbent means 12, it is also configured to retain any bodily fluid that has penetrated to the absorbent element 12 away from the analysis device 34 thereby preventing bodily fluid contaminated by the absorbent element 34 from falsifying an analysis of the analysis device 34. Smith is silent as to the construction of the absorbent element.

However, Rock teaches a textile fabric from which conventional underwear may be made, the textile comprising a super absorbent fiber, such as a copolymer of acrylic acid (col. 3, line 44-col. 4, line 2; col. 5, lines 45-51 of Rock), wherein super absorbent polymer materials are, as disclosed by the applicants, materials which give off substances into bodily fluid and thereby changes the composition of the bodily fluid (p.5,

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lines 3-7 of the instant specification). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the material of Rock as that of the absorbent element of Smith, since Smith discloses the absorbent element to be an undergarment, and Rock teaches a material from which such an undergarment may be made.

As to the language "single use" on line 1 of claim 1 and "disposable" on line 2 of claim 1", the applicant should note that this is merely "intended use" language which cannot be relied upon to define over Smith et al. in view of Rock, since the reference teaches all of the claimed elements and their recited relationships. See *Ex parte Masham* 2 USPQ 2nd 1647. The absorbent element 12 of Smith et al., as modified, is certainly capable of being used once and/or thrown away if a user so desires, and the language "single use" or "disposable" fails to impart any structural difference between the invention of claim 1 and that described by Smith et al., as modified.

Regarding claims 2, 6-9, and 11-14, the separating means 26, 28 is part of an insert 10, wherein the insert 10 which is an area of the hygiene item separated by the separating means 26, 28 from the remainder of the absorbent element 12 (figs. 1 and 2 of Smith).

With further regard to claim 6, the insert 10 is delineated by the separating means 26, 28, part of which comprises a fluid-impermeable film (col. 5, lines 1-5 of Smith).

With further regard to claim 7, the insert 1 is essentially flush-mounted with the upper side of the absorbent element 12 facing the body (figs. 1-3 of Smith).

With further regard to claims 8 and 9, the analysis means 34 is positioned up against one side 28 of the separating means 26, 28 (figs. 2 & 3 of Smith). With further regard to claims 9 and 15, a side 26 of the separating means 26, 28, against which the analysis device 34 is disposed, allows visual reading of a color change in the analysis means 45 (col. 5, line 66-col. 6, line 10 of Smith), wherein the analysis means 34 and the side 26 of the separating means 26, 28 function as a visual display unit.

With further regard to claims 11 and 12, the separating means 26, 28 containing the analysis device 34 is separable from the hygiene item 12 and is detachably fastened to the hygiene item 12 by means of an adhesive (col. 6, lines 41-44 of Smith).

With further regard to claim 13, the insert 10 containing the analysis device 34 has a fluid absorbing and transport layer which transfer the bodily fluid to the analysis device, wherein the fluid absorbing and transport layer comprises cellulose fibers (col. 5, lines 16-26 of Smith).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Rock, as applied to claims 1, 2, 6-9, and 11-14 above, and further in view of US Patent No. 4,114,621 to Mims, Jr. Smith, as modified, fails to describe the insert having sidewalls or the edges of the insert being folded over on an upper side. Mims, Jr. teaches an insert 11, designed to be placed in an absorbent element 10, similar to that of Smith, as modified. The insert features sidewalls 45 extending up on a side facing the body (col. 3, lines 37-38; figs. 4 & 6 of Mims, Jr.) Figure 6 shows these sidewalls being formed by the edges of surface 34 of the insert 11 being folded over on an upper side. Therefore, it would have been obvious to one of ordinary skill in the art at the time

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of invention to combine the sidewalls of Mims, Jr. with the item of Smith et al. in order to further reduce the chance of leakage from the insert to the absorbent element (col. 3, lines 37-38 of Mims, Jr.)

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Rock and Mims, Jr., as applied to claim 4 above. Smith, as modified, fails to teach the edges of the insert being folded over on an upper side of the analysis device. However, it appears that the folded edges of Smith in view of Rock and Mims, Jr. would be folded over an upper side of the analysis device if the folds were large enough. The applicant has not disclosed that the size of the folded edges solves any stated problem or serves any particular purpose. Moreover, it appears that the hygiene item would perform equally well with folded edges of any reasonable size. Accordingly, the recitation that the edges are folded over on an upper side of the analysis device is deemed to be a design consideration that fails to patentably distinguish over the prior art of Smith in view of Rock and Mims, Jr.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Rock, as applied to claims 1, 2, 4-6, 6-9, and 11-14 above, and further in view of US Patent 4,738,674 to Todd et al. While Smith et al. teaches an upper layer of the separating means 26 allowing the color of the display unit 36 to be visualized by the wearer through the layer of the separating means 26, the reference fails to describe layer 26 as being transparent. However, Todd discloses an analysis device 10 having a display unit 24 providing a color change as an indication of analysis results, the display unit is immediately adjacent a transparent outer layer of separating means 14 (figs. 1 &

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2; col. 5, lines 26-28 & 57-60 of Todd). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a transparent layer as the upper side of the separating means of Smith et al., as modified by Rock, since Smith, as modified, teaches an upper layer that allows visualization of the display unit through the separating means and Todd et al. describes that a transparent material would be suitable for such a visualization.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, and 4-14 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 1/14/05 with regard to claim 15 and with regard to certain details regarding the Smith reference, which is relied upon in the rejections presented above, have been fully considered but they are not persuasive.

With regard to the rejection of claim 15 as being anticipated under 35 U.S.C. 102(e) by the Smith reference, the applicant maintains that Smith fails to teach or suggest a single-use hygiene item that includes an absorbent element composed of an absorbent material that gives off substances when contacted with bodily fluid. However, as stated in the previous Office action and above, claim 15 does not positively recite the absorbent element, and in fact is directed only to the analysis device, as stated in the preamble of the claim. As a result, the only importance imparted by limitations regarding the single-use hygiene item is that the analysis element comprises a means for maintaining the analysis device in contact with a single-use hygiene item, as recited in the claim.

With further regard to the Smith reference, the applicant contends that “the term ‘disposable’ used in the hygiene article art clearly describes in structural terms that a respective article is configured and assigned for one-time use only and for discarding thereafter” (see 1st full paragraph, p. 6 of the applicant’s arguments filed 1/14/05). As noted in the above rejection and in previous Office actions, the term “disposable” is considered “intended use” language. The applicant has failed to show that the term imparts any structural limitation that define over the item described by Smith in view of Rock and instead relies on differentiating the claimed invention from the item of Smith, as modified, by how the claimed invention is used (method of using the invention) rather than by any structural limitations. Moreover, the panty 12 disclosed by Smith is fully capable of such use as a “disposable” item. That Smith lacks an explicit teaching of such disposal, as noted by the applicant, does not disprove the item’s capability of being disposed after use.

Regarding the applicant’s argument that Smith fails to facilitate direct impingement of a portion of the bodily fluid passed by the user into contact with the analysis means separate from contact with the absorbent element (see lines 5-8 of p. 7 of the arguments filed 1/14/05), the applicant has failed to point out how Smith fails to teach this feature. The applicant is directed to the rejection above as to the combination of Smith with Rock disclosing an analysis device that facilitates such direct impingement of bodily fluid.

Regarding the applicant’s statement on lines 8-10 on p. 7 of the arguments filed 1/14/05, the applicant should note that the claim 1 does not recite an analysis device

configured for such essentially fluid-tight separation. Instead, the claim language essentially recites, "A single-use hygiene item comprising:. . . means for disposing . . . , and configured for separating the bodily fluid in the analysis device to be analyzed from the disposable absorbent element in an essentially fluid-tight manner", reflecting that the separating means is configured for such essentially fluid-tight separation, not the analysis device. Additionally, the applicant's argument that bodily contour of a user can deform the Smith device thereby compromising any partial fluid imperviousness and containment functions present in that device (see first full paragraph of p. 7 of the arguments filed 1/14/05) is unconvincing, especially since Smith teaches that the element and the liquid impervious layer 28 may be designed to conform to a user's bodily contour (col. 5, lines 42-47 of Smith). Therefore, Smith, as modified by Rock, does indeed teach means configured for separating the bodily fluid in the analysis device to be analyzed from the disposable absorbent element in an essentially fluid tight manner, as claimed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,354,289 to Mitchell et al.

US Patent No. 4,507,121 to Leung.

US Patent No. 5,947,943 to Lee

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Patricia Mallari
Patent Examiner
Art Unit 3736


ROBERT L. NISSEN
PATENT EXAMINER